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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,335	05/20/2005	Piero Del Soldato	026220-00048	9814
4372	7590	02/24/2010		
ARENT FOX LLP 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036			EXAMINER BADJO, BARBARA P	
			ART UNIT	PAPER NUMBER
			1628	
			NOTIFICATION DATE	DELIVERY MODE
			02/24/2010 ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com  
IPMatters@arentfox.com  
Patent\_Mail@arentfox.com

### Office Action Summary

**Application No.**

10/501,335

**Applicant(s)**

DEL SOLDATO ET AL.

**Examiner**

Barbara P. Badio

**Art Unit**

1628

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-26 is/are pending in the application.
- 4a) Of the above claim(s) 9-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/CD)  
Paper No(s)/Mail Date 12/10/2009
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

**Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Status of the Application***

2. Claims 8-26 are pending in the present application. Claims 9-25 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 8 and 26 stand rejected as discussed below.

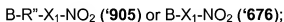
***Double Patenting***

3. **The rejection of claim 1 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent Nos. 7,056,905 and 6,610,676 is made moot by the cancellation of the instant claim.**
4. **The rejection of claims 8 and 26 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent Nos. 7,056,905 and 6,610,676 is maintained.**

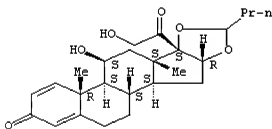
Applicant argues unexpected results based on the claimed compound and the precursor, budesonide, in the treatment of respiratory pathologies characterized by broncho-obstructive events. Applicant also argues the claimed compound is a more potent anti-inflammatory agent and has no effect on 24 hour urinary cortisol versus

budesonide. Based on said results, applicant argues the claimed compound is unobvious and the double patenting is improper. Applicant's argument was considered but not persuasive for the following reasons.

The issue of double patenting is based on whether the claimed compound is an obvious variant of the prior art claim(s). Here, the claims of the cited patents recite compounds of formula:

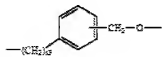


wherein B in each reference can be budesonide



(see claim 2, '905; see claim 2, line 2, '676)

and  $\text{X}_1$  can be



wherein  $n_1$  is an integer from 0 to 3

(see claim 1 of both '905 and '676). The fact that

applicant has discovered that budesonide and budesonide 21-(4'-nitrooxymethyl) benzoate have different properties does not make said compound unobvious in view of the claims of the cited patents.

In summary, the finding of differences in the properties of budesonide and budesonide 21-(4'-nitrooxymethyl) benzoate does not make the claimed compound unobvious in view of the claims of the cited patents.

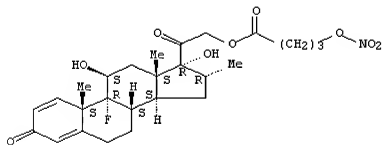
For this reason and those given in the previous Office Action, the rejection of claims 8 and 26 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent Nos. 7,056,905 and 6,610,676 is maintained.

***Claim Rejections - 35 USC § 103***

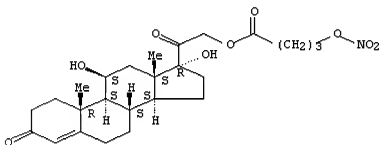
- 5. The rejection of claim 1 under 35 USC 103(a) over Del Soldato (WO 98/15568) is made moot by the cancellation of the instant claim.**
  
- 6. The rejection of claims 8 and 26 under 35 USC 103(a) over Del Soldato (WO 98/15568) is maintained.**

Applicant argues unexpected results based on the claimed compound and the precursor, budesonide, in the treatment of respiratory pathologies characterized by broncho-obstructive events. Applicant also argues the claimed compound is a more potent anti-inflammatory agent and has no effect on 24 hour urinary cortisol versus budesonide. Based on said results, applicant argues the claimed compound is unobvious. Applicant's argument was considered but not persuasive for the following reason.

For a showing of unexpected and/or unobvious results comparison has to be between the claimed compound and the closest prior art compound. Del Soldato teaches nitrate esters of corticosteroids and exemplifies:



and



. Applicant's comparison is between the claimed nitrate ester of budesonide and budesonide which is not the closest prior art compound taught by Del Soldato.

Secondly, Del Soldato teaches (a) the compounds, i.e., nitrate esters of corticosteroids, are useful in the treatment of pathologic conditions where corticosteroids are used but with increased benefits and (b) the nitrate esters of corticosteroids show an improved therapeutic profile, i.e., they have high activity combined with low side-effects, as compared to the corresponding corticosteroids (see page 1, paragraph 4). Therefore, applicant showing that budesonide 21-(4'-

nitrooxymethyl)benzoate, i.e., a nitrate ester of corticosteroids, is more potent than budesonide is not considered unobvious and/or unexpected.

In summary, (a) the comparison is not between the claimed compound and the closest prior art compound and (b) the showing is not considered unobvious and/or unexpected.

For these reasons and those given in the previous Office Action, the rejection of claims 8 and 26 under 35 USC 103(a) over Del Soldato (WO 98/15568) is maintained.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiry***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/  
Primary Examiner, Art Unit 1628